

IN THE UNITED STATES DISTRICT COURT FOR THE
WESTERN DISTRICT OF MISSOURI
CENTRAL DIVISION

DAVID ZINK, *et al.*,

Plaintiffs,

v.

GEORGE A. LOMBARDI, *et al.*,

Defendants.

Case No. 12-4209-CV-C-BP

THIS IS A CAPITAL CASE

**Execution scheduled for
12:01 a.m. Feb. 26, 2014**

**PLAINTIFF MICHAEL TAYLOR’S REPLY IN
FURTHER SUPPORT OF MOTION FOR STAY OF EXECUTION
BASED ON ABSENCE OF LAWFUL MEANS OF EXECUTION**

Defendants have now disclosed, less than a week before they wish to execute Taylor, that a completely new – and completely unknown – player has joined their team to perform the key function of providing the lethal drugs. They have “arranged with a [new] pharmacy,” they say, “to supply pentobarbital for Taylor’s execution.” (Opp’n at 2)

Utterly nothing is known about this pharmacy. Has it been cited for violating federal and state laws more or less often than the previous pharmacy? Does it also send its drugs, to be tested for purity and sterility, to a laboratory that approved a batch of tainted steroids that killed over 60 people? For that matter, does the pharmacy test its drugs at all?

Defendants ask for a leap of faith: “There is no reason to believe that the execution will not,” they say, “be rapid and painless.” (Opp’n at 2) But Taylor “is not limited to taking Defendants’ word that his rights will not be violated by what they propose to do.” *Oken v. Sizer*, 321 F.Supp.2d 658, 665 (D.Md. 2004). He has a right to meaningful notice and opportunity to object; that is impossible now.

ARGUMENT

Executing Taylor in Less Than a Week Would Violate His Right to Due Process of Law

“For more than a century the central meaning of procedural due process has been clear: ‘Parties whose rights are to be affected are entitled to be heard; and in order that they may enjoy that right they must first be notified.’ It is equally fundamental that the right to notice and an opportunity to be heard ‘must be granted at a meaningful time and in a meaningful manner.’” *Fuentes v. Shevin*, 407 U.S. 67, 80 (1972) (citations omitted).

Moreover, “‘fairness can rarely be obtained by secret, one-sided determination of facts decisive of rights. . . . [And n]o better instrument has been devised for arriving at truth than to give a person in jeopardy of serious loss notice of the case against him and opportunity to meet it.’” *Id.* at 81 (citation omitted).

Since this litigation began, defendants have asserted a prerogative to make a “secret, one-sided determination of facts decisive of [plaintiffs’] rights.” They will decide, without prior notice, how plaintiffs are to be killed. They will inform plaintiffs of that procedure when they feel like it. They will change that procedure when they feel like it. They will respond to discovery requests when, and if, they feel like it. They will shroud their “execution team” – liberally defined to include pharmacies hundreds of miles away – in total secrecy, as two Eighth Circuit judges say, “hidden behind the hangman’s hood.” (Exhibit A at 15)

Likewise, if history repeats itself, defendants will offer their one-sided analysis of the drugs, tested by their industry-captured laboratory, to argue that plaintiffs need not know who made the drugs, how they were made, what they are

made of, or where the ingredients came from.

Indeed, defendants now claim – contrary to their deposition testimony last month – that even the drug supplier’s *supplier* is a “state secret.” (Exhibit B at Answer 9(c)) Defendants disclaimed this just last month (Exhibit C at 72) and cite no law that actually supports their brand-new claim of secrecy. This baseless flip-flop, that the supplier of the raw ingredients for the pharmacy is suddenly a member of the “execution team,” raises obvious and reasonable questions: Just why do defendants want to keep this a secret? Is it because the pharmacy’s supplier has committed unlawful or unethical acts? Or is not regulated by the FDA? Or is one of the Indian factories that “suffer[s] from serious quality control problems?” (Exhibit D) Or is one of the Chinese factories that supplies raw ingredients for American drugs but is similarly beyond the FDA’s effective reach? (Exhibit D) Defendants never claimed this was a secret before. Why now?

Defendants refuse to disclose anything about their new drug supplier, or anything about the drug’s origins or testing (if any) in time for Taylor to have either meaningful notice of what they wish to pump into him or an opportunity to meaningfully object. Taylor’s right to judicial review cannot seriously be honored by defendants now introducing, after having literally years to plan for this, a totally unknown party to play a key role and then plowing through three levels of courts in less than a week.

It is unsettling, moreover, that defendants would even try. Whether one supports or opposes capital punishment, there is something sordid about rushing to execute a person less than a week after switching the supplier of the lethal drug—especially where, as here, the drug is effectively unregulated and experimental and

has already provided cause for alarm: “I feel my whole body burning,” Michael Wilson said within seconds of pentobarbital being injected into him. Perhaps those drugs came from the pharmacy defendants have now retained?

Defendants complain that they have switched suppliers at the eleventh hour only because Taylor persuaded the old pharmacy not to provide drugs to kill him. The basis of Taylor’s suit against the old pharmacy, of course, was the fact that its provision of execution drugs was unethical at best and unconstitutional at worst. Defendants have no compunction about what they are doing; the pharmacy did.

The Court should proceed with caution here, and not simply because Taylor suggests it. “Because of the understandable, self-interested fallibility of litigants, a court does not decide a dispute until it has had an opportunity to hear both sides—and does not generally take even tentative action until it has itself examined the support for [a party’s] position.” *Fuentes*, 407 U.S. at 83. As to the new player, defendants essentially say: We’re not going to tell you anything material in time to make an informed judgment but, trust us, everything will be fine. The Court should reject this invitation to substitute one-sided assurances for judicial review.

This is especially so because defendants’ assurances are baseless. “There is no reason to believe that the execution will not,” they say, “be rapid and painless.” (Opp’n at 2) Yet they ignore the fact that the reliability and potency of compounded pentobarbital cannot be assured from execution-to-execution or from batch-to-batch. (Docket 338-42) And here, of course, Taylor and the Court are faced not simply with a different batch of the drug but with an entirely different pharmacy, which may or may not be using the same raw ingredients as the last pharmacy. Dr. Sasich has explained: “The effects of the state’s drug may vary

considerably from execution to execution for a number of reasons.” (Docket 338-42 at 1) These include the fact that the drugs to be used in one particular execution are not necessarily from the same batch as previous executions. *Id.* And all of the many hazards Dr. Sasich has identified “with respect to compounded pentobarbital remain from batch to batch and compounding pharmacy to compounding pharmacy.” *Id.*

“Given what is at stake,” one judge also faced with a last-minute change concluded, “the Court simply cannot comply fully with that directive [to assess a revised protocol] in time to render a reasoned decision and permit adequate appellate review.” *Morales v. Cate*, 2010 WL 3835655 at *4 (N.D.Cal. 2010). There, as defendants claim here, the old and new protocols were “remarkably similar.” *Id.* at *3. “Given what is at stake,” the judge nonetheless granted a limited stay of execution to meaningfully assess the revised protocol: “The Court fully intends to undertake that review now, and to do so as quickly as is reasonably possible.” *Id.* at *5. The fact that this would delay any execution until “the first quarter of 2011” – which was three months later – “means that such a time line will have minimal effect on Defendants’ longterm interests.” *Id.*

The same is true here. It is reasonable to stay Taylor’s execution until he and the Court can conduct the same inquiry that was done with respect to the prior pharmacy: Has it broken the law? How does it prepare the drugs? What, exactly, is in them? How are they stored? What analysis, if any, is performed to ensure they pose no risk of inflicting substantial pain and suffering? These are all reasonable questions that any litigant – capital inmate or not – has the right to ask and have answered before an untested and unique compound is injected into him.

Moreover, answering these questions is essential to enforcing Taylor's due-process right to meaningful notice and meaningful opportunity to be heard. As defendants ignore, scores of courts have rejected similarly hasty efforts to execute people where the information was less than complete. *See Arthur v. Thomas*, 674 F.3d 1257, 1262 (11th Cir. 2012) (per curiam) ("[T]he district court committed reversible error in dismissing Arthur's Eighth Amendment claim without any opportunity for factual development, including discovery between the parties."); *Reynolds v. Strickland*, 583 F.3d 956, 957 (6th Cir. 2009) (granting stay where "serious and troubling difficulties" during past executions raised concerns over the "competence of the lethal injection team"); *Cooey v. Kasich*, 801 F. Supp. 2d 623, 655 (S.D.Ohio 2011) (granting stay where there was evidence of "a troubling pattern of disregarding the very protocol that is supposed to control and provide safeguards for the execution process"); *Moeller v. Weber*, 2011 WL 288516 at *1 (D.S.D. 2011) (refusing to curtail "discovery concerning the plan for carrying out executions in light of the shortage of sodium thiopental"); *Morales v. Cate*, 2010 WL 3835655 at *3 (N.D.Cal. 2010) (granting stay where condemned inmate raised questions about "the selection and training of the execution team, the mixing and delivery of the drugs used in executions, and the adequacy and accuracy of execution records"); *Chester v. Beard*, 657 F. Supp. 2d 534, 542-454 (M.D.Pa. 2009) (holding that condemned inmates' allegations of inadequately trained personnel and inadequate safeguards, if true, would demonstrate a substantial risk of serious harm, and giving inmates a chance to factually develop their claims); *Thorson v. Epps*, 2009 WL 1766806 at *1-*2 (N.D. Miss. 2009) (denying motion to dismiss condemned inmates' allegations of executioner incompetence, which, if

true, “plausibly would entitle him to relief,” and noting importance that “the factual record had been completely developed”).

The information here is definitely less than complete. In fact, the only scientific evidence of record states that a drug’s full provenance – which defendants refuse to provide – is essential to determining its safety. As explained by pharmacology expert Dr. Larry Sasich:

The Missouri Department of Corrections has not disclosed any evidence that the API [active pharmaceutical ingredient] in this case was manufactured in an FDA-registered facility. There is also no evidence that the API meets U.S. Pharmacopeia standards required for the finished dosage form: there is no way of knowing the current quality of the API in the bottle, after manufacture and initial testing (if performed), and after supply-chain, repackaging and pharmacy handling. The Department has not disclosed preliminary evidence and additional verification of production in a facility that is registered and inspected by FDA in any compounding process.

Administering such an ingredient introduces an unacceptable risk of harm and is ill-advised.

(Docket157-3 ¶ 27) Anesthesiologist Mark J.S. Heath, M.D., agrees. *See* Docket 157-4 ¶ 10 (“The MDOC has not provided any information about the certification, inspection history, infraction history, or other aspects of the compounding pharmacy. This information would be essential to properly assessing the provenance of the pentobarbital.”).

Ignoring these facts, and the precedents above, defendants cite a single case, *Williams v. Hobbs*, 658 F.3d 842 (8th Cir. 2011), for their claim that they may

change the drug supplier – without providing any material information – and execute Taylor less than a week later. *Williams* says nothing of the kind.

First, the *Williams* plaintiffs were not facing imminent execution: all had received stays. *Id.* at 848. As such, the Court neither addressed nor resolved the question here: whether a state may switch to a completely unknown supplier of a completely untested drug and use that drug to kill the plaintiff a few days later.

Second, the protocol in *Williams* had already been held constitutional under the Eighth Amendment. *Id.* at 852. Here, of course, that is not the case.

Third, the *Williams* litigants’ fears of possible future misconduct were speculative: “The prisoners have not demonstrated that the Director has departed from this protocol. Rather they speculate the [*sic*] he might depart from it in the future.” *Id.* Here, on the other hand, there is no need for speculation because defendants have already made a last-minute switch by introducing a new player to perform a key function in the protocol: provision of the lethal drugs.

Fourth, the *Williams* litigants were fishing “to *discover* potential claims,” *id.* (emphasis in original), whereas Taylor has already stated his claim: defendants’ constant, last-minute, and effectively secret changes to how they propose to execute him violates his due-process right to meaningful notice of, and opportunity to challenge, their attempt to take his life. *See* Second Amended Complaint (Docket 338) at Claims VII and VIII.

Fifth, the *Williams* Court expressed concern over a “situation occurring where the prisoners must submit a FOIA request every day in order to be sure that the protocol has not changed prior to the execution date.” *Id.* at 850. But, unlike here, the defendants in *Williams* assured the Court they would provide timely

notice of any changes: “The state’s counsel stated at oral argument that he could not imagine a situation in which he would not be able to call the prisoners’ counsel personally to inform them of a change in the protocol. This at least provides the prisoners with some assurance that they will receive a timely response to their request for information regarding a new protocol.” *Id.* Here, by contrast, the facts are virtually the opposite. Defendants and their counsel have effectively eschewed the undertaking the Eighth Circuit relied on from defendants’ counsel in *Williams*. What the district court and the Eighth Circuit found to be speculative in *Williams* was a fact to which this Court is a witness— and a fact made worse by yesterday’s disclosure of a new supplier. Far from it being speculative that defendants will make last-minute changes while withholding information to which plaintiffs and this Court are entitled, that has already come to pass.

Given the precedents above, which defendants ignore, Taylor has a “significant possibility” of succeeding on his due-process claim. *Hill v. McDonough*, 547 U.S. 573, 584 (2006). Moreover: “The right to be heard does not depend upon an advance showing that one will surely prevail at the hearing. . . . It is enough to invoke the procedural safeguards of the Fourteenth Amendment that a significant property interest is at stake, whatever the ultimate outcome of a hearing.” *Fuentes*, 407 U.S. at 87. Here, of course, it is not Taylor’s “property interest” that is at stake but his very life. He has a fundamental constitutional right not to be deprived of that life without due process of law.

This right cannot be honored when, after 18 months of litigation, defendants introduce an entirely unknown drug supplier and propose to use that supplier’s entirely unknown product to kill Taylor a few days later. Due process requires a

reasonable stay of execution– so Taylor has meaningful notice and opportunity to object, and so this Court may meaningfully adjudicate his objections.

CONCLUSION

The Court should stay Taylor’s execution until he has meaningful notice of – and opportunity to challenge – Missouri’s plan to take his life.

Respectfully submitted,

SEAN K. KENNEDY
Federal Public Defender

DATED: February 20, 2014

By s/ Matthew B. Larsen
MATTHEW B. LARSEN
Deputy Federal Public Defender

EXHIBIT A

**UNITED STATES COURT OF APPEALS
FOR THE EIGHTH CIRCUIT**

No: 13-3664

David Zink, et al.

Allen L. Nicklasson

Appellant

John C. Middleton, et al.

v.

George A. Lombardi, et al.

Appellees

Appeal from U.S. District Court for the Western District of Missouri - Jefferson City
(2:12-cv-04209-NKL)

AMENDED ORDER

The petition for rehearing en banc, the petition for rehearing by panel and the motion for stay of execution are denied as moot. Judge Duane Benton did not participate in the consideration or decision of this matter.

BYE, Circuit Judge, with whom KELLY, Circuit Judge, joins, dissenting.

At approximately 10:52 p.m. on December 11, 2013, Missouri executed Allen Nicklasson before this court had completed its review of Nicklasson's request for a stay of his execution, a request he brought in a pending action challenging the constitutionality of Missouri's execution protocol. That bears repeating. Missouri put Nicklasson to death before the federal courts had a final say on whether doing so violated the federal constitution.

Missouri has a well-documented history of attempting to execute death row inmates before the federal courts can determine the constitutionality of the executions. In 1983, Missouri set an execution date for Doyle Williams before the time had run for Williams to petition the Supreme Court for direct review of his conviction and death sentence. Supreme Court Justice Harry Blackmun stayed the execution, specifically advising Missouri that a "defendant must have at least one opportunity to present to the [Supreme Court] his claims that his death sentence has been imposed unconstitutionally." Williams v. Missouri, 463 U.S. 1301, 1301-02 (1983).

Just a few months later, however, Missouri set the execution dates of four death row inmates – Samuel Lee McDonald, Leonard Marvin Laws, Thomas Henry Battle, and George Clifton Gilmore – before the time had run for the filing and disposition of a petition for certiorari on direct review of the men's convictions and death

sentences. In the order entering a stay of the executions, Justice Blackmun unequivocally stated that

[e]very defendant in a state court of this Nation who has a right of direct review from a sentence of death, no matter how heinous his offense may appear to be, is entitled to have that review before paying the ultimate penalty. The right of review otherwise is rendered utterly meaningless. It makes no sense to have the execution set on a date . . . before [judicial] review is completed.

McDonald v. Missouri, 464 U.S. 1306, 1307 (1984).

Additionally, Justice Blackmun reminded Missouri of what he said in Williams:

I thought I had advised the Supreme Court of Missouri once before, in Williams, that, as Circuit Justice of the Circuit in which the State of Missouri is located, I, upon proper application, shall stay the execution of any Missouri applicant whose direct review of his conviction and death sentence is being sought and has not been completed. I repeat the admonition to the Supreme Court of Missouri, and to any official within the State's chain of responsibility, that I shall continue that practice. *The stay, of course, ought to be granted by the state tribunal in the first instance, but, if it fails to fulfill its responsibility, I shall fulfill mine.*

Id. (emphasis added).

Thirteen months after Justice Blackmun's admonition, Missouri set an execution date for Walter Junior Blair. Prior to his execution date, Blair had filed a

petition for writ of habeas corpus in federal district court. Blair then filed a motion with the Missouri Supreme Court requesting a stay of his execution to give him a meaningful opportunity to exercise his constitutional right of federal habeas review. The Missouri Supreme Court nonetheless summarily denied the request for a stay. A federal district court was thus required to step in and stay the execution. See Blair v. Armontrout, 604 F. Supp. 723, 723 (W.D. Mo. 1985). In so doing, the court noted that

[b]y refusing the petitioner's request for a stay of execution, the Missouri Supreme Court has in effect authorized the execution of a condemned prisoner without affording him the opportunity to exercise his constitutional right of federal habeas corpus review. In so doing, the Missouri Supreme Court ignored its responsibility to stay executions while federal judicial review is pending.

Id. at 724. The district court reiterated the admonitions Justice Blackmun had given Missouri in Williams and McDonald, and expressly held "[a] state prisoner sentenced to death is constitutionally entitled to habeas corpus review," id. at 725, adding that the principle of comity (i.e., federal courts first affording states the opportunity to perform their constitutional duties) "will be jeopardized if the Missouri Supreme Court continues to ignore its well-defined responsibility concerning requests for stays of execution due to pending federal review. Since the Missouri Supreme Court has failed to accept its responsibility, I shall accept mine." Id.

Less than a year after Blair, Missouri set January 6, 1986, as the execution date for Gerald M. Smith. At the time, Smith was a death row inmate whose competency was in question based upon his indecision about whether to pursue available state and federal remedies attacking his conviction and death sentence, or abandon his legal proceedings and proceed with his execution. Smith's brother, Eugene Smith, filed a next-friend petition in a Missouri state court seeking a determination of his brother's competency before Missouri proceeded with the execution; Eugene also filed a motion in the Missouri Supreme Court to stay the execution until his brother's competency could be determined. The Missouri Supreme Court summarily denied the request for a stay "in one line and without any explanation." Smith By and Through Smith v. Armontrout, 626 F. Supp. 936, 938 (W.D. Mo. 1986). After Eugene obtained a ruling in the state trial court that his next-friend petition was a valid action under Missouri law, the Missouri Supreme Court postponed the execution for nine days, but ultimately "issued an order which, in effect, stated that the next-friend [proceeding] . . . was a legal nullity and that no further extensions of Gerald Smith's execution date would be granted." Id.

Once again, a Missouri litigant was required to turn to the federal courts to ensure that Missouri complied with constitutional requirements mandated by the United States Supreme Court before carrying out an execution. See Rees v. Peyton,

384 U.S. 312, 313-14 (1966) (explaining the competency procedures which any court of this nation, state or federal, must follow when a death row inmate announces an intention to abandon further appeals and proceed with an execution). In staying Missouri's execution of Gerald Smith until his competency could be determined, the federal district court stated "it becomes painfully obvious that the Missouri Supreme Court's refusal to stay Gerald Smith's execution pending a competency determination . . . had no basis in fact nor in law, but was merely an expedient way of washing its hands of the matter and passing the buck to the Federal courts." Smith, 626 F. Supp. at 940. The district court further noted "[t]his is not the first time that the Missouri Supreme Court has passed the buck to the Federal courts by refusing to perform its legal obligation to stay an execution . . . when the law required a stay to permit post-conviction appeals to be heard in an orderly manner," id., and referred to the prior Williams, McDonald, and Blair cases.

The district court also commented on the necessary and inevitable tension which exists between a state's choice to utilize death as a penalty on one hand, and the safeguards our Founding Fathers saw fit to include in our federal constitution on the other:

This Court is aware that many members of the public are frustrated with what seems to be inordinate delay in the processing of appeals by death row inmates. Indeed, many people believe that there should be no appeals whatsoever following the jury's imposition of the death

sentence. *The law, on the other hand, provides that certain procedures must be followed before a death sentence may be carried out.* Although it may not win a popularity contest in any given case, this scheme was adopted to ensure that *every individual would be accorded due process of law.*

Id. at 940 n.3 (emphasis added).

In May 2005, Missouri death row inmate Vernon Brown challenged the three-chemical protocol Missouri used in its executions at the time. Brown was one of the first death row inmates to participate in what subsequently became a multi-state challenge to this three-chemical protocol, incited in large part by the publication of an April 2005 article in the medical journal *The Lancet*. The article analyzed autopsy toxicology results from forty-nine executions where the three-chemical sequence of sodium pentothal¹ (a sedative), pancuronium bromide (a paralytic), and potassium chloride (a very painful drug which induces a heart attack) was used to carry out the executions. The article's authors essentially concluded that in almost half of the autopsies examined (43%), the amount of sedative used in the executions would have been insufficient to render the inmate unconscious. "In other words, the use of this three-chemical sequence results in a possibility the person to whom it is administered will be conscious when the inherently painful potassium chloride takes effect, yet no one will know because of the paralytic effects of the pancuronium

¹Sodium pentothal is sometimes referred to as thiopental.

bromide." Brown v. Crawford, 408 F.3d 1027, 1028 (8th Cir. 2005) (Bye, J., dissenting). The evidence Brown asked us to consider included the fact that nineteen states had passed laws banning the use of a similar protocol to euthanize animals. Brown alleged Missouri is "using a combination of chemicals they knew or should have known would cause an excruciating death when they were telling the public it was like putting a dog to sleep, when their own veterinarians would lose their licenses for using the same chemicals on a stray." Id. (quoting Brown v. Crawford, No. 4:05-VV-746-CEJ, Motions for Temporary Restraining Order at 19).

The article in *The Lancet* had been published just a month before Brown's execution date. He relied upon it to bring an eleventh-hour challenge to his execution, merely asking Missouri to disclose the level of sodium pentothal it would use in his execution before executing him – hardly an onerous request. In refusing to disclose information about the dosage levels used in its execution protocol, Missouri trumpeted the need to proceed with Brown's execution post haste in order to provide the families of the victims of his crimes with closure. Against my dissent, the Eighth Circuit said Missouri could execute Brown without first disclosing whether its protocol utilized an adequate dosage of sodium pentothal. Brown was strapped to a gurney at 11:30 p.m., and left there for three hours before a divided Supreme Court finally denied his request for a stay and allowed Missouri to proceed with his execution.

Missouri death row inmate Michael Anthony Taylor also challenged Missouri's use of the three-chemical protocol. In more reflective deliberations not burdened by the eleventh-hour nature of Vernon Brown's challenge, the federal courts handling Taylor's suit understandably recognized he, along with other Missouri death row inmates, were entitled to know the dosage levels Missouri used in its execution protocol before Missouri could execute them.

Taylor discovered numerous and significant problems with Missouri's execution protocol, including inconsistencies between the amounts of sodium pentothal Missouri claimed to be using in every execution, and chemical dispensary logs which showed much lower amounts of the sedative actually being used in several executions. See Taylor v. Crawford, No. 05-4173-CV-C-FJG, 2006 WL 1779035, at *3 (W.D. Mo. June 26, 2006). Incredibly, Missouri had not adopted a written protocol for its executions. Even more incredibly, Missouri gave unfettered discretion to an *admittedly dyslexic physician* to implement the state's unwritten protocol, *including the responsibility of correctly mixing the drugs used in executions*. Id. at *4-8. The district court's observations bear repeating here:

After learning more about how executions are carried out in Missouri, through the interrogatories submitted to the John Doe defendants, reviewing the chemical dispensary logs, reviewing the videotape of the execution chamber and listening to the testimony of John Doe I, and to the testimony of the other expert witnesses at the June 12-13, 2006 hearing, it is apparent that there are numerous problems. For example,

there is no written protocol which describes which drugs will be administered, in what amounts and defines how they will be administered. John Doe I testified that he came up with the current protocol. John Doe I also testified that he felt that he had the authority to change or modify the formula as he saw fit. It is apparent that he has changed and modified the protocol on several occasions in the past. He has reduced the amount of thiopental given from 5.0 grams to 2.5 grams and has also changed the location on the inmate's body where the drugs were administered. It is obvious that the protocol as it currently exists is not carried out consistently and is subject to change at a moment's notice.

The Court is also concerned that John Doe I possesses total discretion for the execution protocol. Currently, there are no checks and balances or oversight, either before, during or after the lethal injection occurs. No one monitors the changes or modifications that John Doe I makes. John Doe I even testified that the Director of the Department of Corrections, Mr. Crawford, has no medical or corrections background, and that he is "totally dependent on me advising him." (John Doe Depo. p. 64).

In addition to the fact that there is no oversight and the responsibility for making changes or adjustments is completely vested in one individual, the Court also has concerns about John Doe I's qualifications. John Doe I readily admitted that he is dyslexic and that he has difficulty with numbers and oftentimes transposes numbers. John Doe I testified "it's not unusual for me to make mistakes. . . . But I am dyslexic and that is the reason why there are inconsistencies in my testimony. That's why there are inconsistencies in what I call drugs. I can make these mistakes, but it's not medically crucial in the type of work I do as a surgeon." (John Doe Depo. p. 25). The Court disagrees and is gravely concerned that a physician who is solely responsible for correctly mixing the drugs which will be responsible for humanely ending the life of condemned inmates has a condition which causes him confusion with regard to numbers. As the Court has learned, the process of mixing the three different drugs and knowing the correct amount of the drugs to dissolve in the correct amount of solution involves precise measurements and the ability to use, decipher, and not confuse numbers. Although John Doe I does not feel this is crucial in the type of work he does as a surgeon, it

is critical when one is mixing and dissolving chemicals for a lethal injection.

In addition, John Doe I testified that although he is not an anesthesiologist, he monitors the anesthetic depth of an inmate by observing the inmate's facial expression. However, as can be seen from the videotape of the execution chamber, when the inmate is lying on the gurney in the execution room, the inmate is facing away from the Operations room where John Doe I is located. Additionally, it is dark in the Operations room and there are blinds on the window which are partially closed and obstruct the view. This would make it almost impossible for John Doe I to observe the inmate's facial expression. This leads the Court to conclude that there is little or no monitoring of the inmate to ensure that he has received an adequate dose of anesthesia before the other two chemicals are administered.

Id. at *7-8. The district court ultimately concluded "Missouri's lethal injection procedure subjects condemned inmates to an unnecessary [and unacceptable] risk that they will be subject to unconstitutional pain and suffering when the lethal injection drugs are administered." Id. at *8. The district court ordered Missouri to prepare a new written protocol for the implementation of lethal injections to ensure compliance with the federal constitution. Id. The Eighth Circuit vacated the injunction entered by the district court to prevent Missouri from proceeding with any executions only after Missouri adopted a detailed written execution protocol, and indicated it would no longer use the services of the dyslexic physician. See Taylor v. Crawford, 487 F.3d 1072, 1077 n.3, 1082-85 (8th Cir. 2007).

II

With this history of Missouri's implementation of the death penalty in mind, I turn to Allen Nicklasson's now-moot challenge to Missouri's more recent, ever-changing execution protocol. Allen Nicklasson was one of a number of Missouri death row inmates who filed suit raising constitutional challenges against an execution protocol Missouri announced on May 15, 2012. The new protocol would utilize just a single drug, propofol, to carry out executions. The inmates filed their lawsuit in Missouri state court, but Missouri's choice to remove it triggered our federal review.

The inmates' challenge to Missouri's execution protocol is no longer about the use of propofol because Missouri has changed the protocol numerous times since May 2012, while still actively scheduling new executions. Joseph Franklin was also one of the death row inmates participating in this constitutional challenge to Missouri's execution protocol. Missouri scheduled, and completed, Franklin's execution on November 20, 2013, notwithstanding the fact it changed the execution protocol no less than five times between August 1, 2013, and November 20, 2103, with the last protocol change occurring just five days before Franklin was executed.

The issues currently involved in this protocol litigation include the fact that Missouri is resorting to secret compounding pharmacies to concoct copycat versions

of the drug pentobarbital to carry out its executions. Applying Hill v. McDonough, 547 U.S. 573 (2006), the district court presiding over the protocol litigation entered a stay of Franklin's execution after concluding the inmates showed "a significant likelihood of success on the merits, a showing of irreparable harm in contrast to relatively little harm to [Missouri], and no fault in the delay of their current case pending before this Court." Zink v. Lombardi, No. 2:12-CV-4209-NKL, 2013 WL 6080358, at *8 (W.D. Mo. Nov. 19, 2013).

With respect to the moving target Missouri kept presenting to the inmates by constantly changing its execution protocol while still going forward with Franklin's execution (and now Nicklasson's), the district court said

[death penalty] litigation is not a game of chess. Hill was intended to be a shield to protect defendants from abusive litigation practices by death row inmates. But it was never intended to be used as a sword permitting defendants to disrupt and delay the litigation process and then complain that time is up. Neither the Plaintiffs nor the Court have been able to address the merits of Plaintiffs' claim that the Defendants have adopted an execution protocol that violates the U.S. Constitution, because the Defendants keep changing the protocol that they intend to use. It would be a substantial departure from the way in which law suits are generally handled by this Court, to allow Defendants to succeed with this strategy. Rather, the pending dispute between the parties should be resolved on the merits after a reasonable opportunity for both sides to be heard, followed by a prompt, final order resolving the dispute. That is how it is normally done in America and it is a system that has worked quite well.

Id. at *6.

I agreed with the district court's analysis and voted to stay Franklin's execution. Although a majority of my colleagues disagreed, and Franklin was allowed to be executed, I still agree with the district court's analysis, which is why I voted to stay Nicklasson's execution as well.

My point, however, in this dissent from the denial of the petition for rehearing en banc of Nicklasson's request for a stay, is not to discuss or rehash the merits of the current protocol litigation. Rather, I feel obliged to say something because I am alarmed that Missouri proceeded with its execution of Allen Nicklasson before this court had even finished voting on Nicklasson's request for a stay. In my near fourteen years on the bench, this is the first time I can recall this happening. In litigation raising a constitutional challenge to his execution, a death row inmate sought a stay of his execution under Hill, and before the federal courts had issued a final decision on the pending request for a stay, Missouri carried out the execution.

While the current protocol litigation is not among the category of cases for which Nicklasson was entitled to an automatic stay of his execution, it was nonetheless a claim that Missouri would violate the federal constitution by executing him. As a result, Nicklasson was entitled to have this court complete its equitable review under Hill to determine whether he was entitled to a stay before Missouri

actually executed him. By proceeding with Nicklasson's execution before our court had completed voting on his petition for rehearing en banc, Missouri violated the spirit, if not the letter, of the long litany of cases warning Missouri to stay executions while federal review of an inmate's constitutional challenge is still pending.

III

Missouri's past history of scheduling executions before a death row inmate has exhausted his constitutional rights of review, using unwritten execution protocols, misrepresenting dosage levels for drugs used in lethal injections, and providing unfettered discretion to a dyslexic physician to mix the drugs and oversee its executions, has earned from this federal judge more than just a healthy judicial skepticism regarding Missouri's implementation of the death penalty. Its current practice of using shadow pharmacies hidden behind the hangman's hood, copycat pharmaceuticals, numerous last-minute changes to its execution protocol, and finally, its act of proceeding with an execution before the federal courts had completed their review of an active request for a stay, has committed this judge to subjecting the state's future implementation of the penalty of death to intense judicial scrutiny, for the sake of the death row inmates involved as well as adversaries and advocates of capital punishment alike.

December 23, 2013

Order Entered at the Direction of the Court:
Clerk, U.S. Court of Appeals, Eighth Circuit
/s/Michael E. Gans

EXHIBIT B

**IN THE UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF MISSOURI
CENTRAL DIVISION**

DAVID ZINK, et al.,)	
)	
Plaintiffs,)	
)	
v.)	No. 2:12-CV-4209
)	
GEORGE LOMBARDI, et al.,)	
)	
Defendants.)	

**DEFENDANT DAVID DORMIRE'S SUPPLEMENTAL ANSWERS FOR
PLAINTIFFS' FOURTH SET OF INTERROGATORIES**

Defendant David Dormire hereby supplements his answers to
Plaintiffs' Fourth Set of Interrogatories as follows:

5. State the date and time of the decisions to commence the execution of
Joseph Franklin and Allen Nicklasson.

**ANSWER: I do not know the exact times. The date for Franklin
was 11/20/13. The date for Nicklasson was 12/11/13. Upon information
and belief, the chronological logs, which were previously produced,
state that Franklin was removed from the holding cell at 5:29 a.m. on
November 20, 2013 and escorted to the execution chamber. Upon
further information and belief, the chronological logs, which were
previously produced, state that Nicklasson was removed from the**

holding cell at 10:15 p.m. on December 11, 2013 and escorted to the execution chamber.

6. Identify each person known to you who was aware that at the time Mr. Franklin's execution commenced, a motion for stay of execution had been filed in the United States District Court for the Western District of Missouri and had not yet been ruled on by the Court.

ANSWER: I have no knowledge of this. Upon information and belief, I believe Director Lombardi stated in his deposition testimony that the Attorney General himself advised that there were no legal impediments to both the Franklin and Nicklasson executions proceeding. I do not know whether, or who, in the Attorney General's Office would have this knowledge.

7. State whether any person made any attempt, or directed anyone else to make an attempt, to notify Mr. Franklin's counsel that the execution was about to commence. If so, identify each such person, describe the date, time and nature of the notification, and indicate whether counsel acknowledged such notice.

ANSWER: I did not make any such notification. Upon information and belief, I am not aware of anyone in the Department of Corrections making such notification.

8. Identify each person known to you who was aware that at the time Nicklasson's execution commenced, there was a petition for rehearing pending in the United States Court of Appeals in the Eighth Circuit and a petition for certiorari lodge with the United States Supreme Court, both seeking stays of execution?

ANSWER: I have no knowledge of this. Upon information and belief, the Department of Corrections relies on advice of its General Counsel, the Attorney General's Office and the Governor's Office in proceeding with any execution.

9. For any substance you represent to be pentobarbital now in the possession of the DOC or which has been in the possession of DOC since July, 2013, please provide the following information. If there has been more than one acquisition of pentobarbital, provide this information for each separate quantity of pentobarbital which has been acquired.

- a. The date the pentobarbital was received by the DOC and the amount received on that date;
- b. The identity of the compounding pharmacy which supplied it;
- c. The identity of the source or sources from which the latter pharmacy obtained each material from which it "compounded" the substance you represent to be pentobarbital;

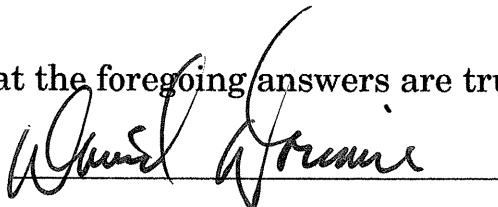
- d. The date the substance you represent to be pentobarbital was compounded/manufactured by the compounding pharmacy;
- e. The expiration or “use by” date of the substance you represent to be pentobarbital;
- f. The basis on which the expiration or “use by” date was determined;
- g. The conditions under which the substance you represent to be pentobarbital was stored at the compounding pharmacy from which you purchased it; and
- h. The date through which you intend to administer your current supplies of purported pentobarbital in executions. If you intend to use different subsets of your supplies through different dates, please indicate.

ANSWER:

- a. 10 grams on 1/14¹⁴
- b. I object to this interrogatory because it seeks information regarding the identity of the compounding pharmacy. This information is confidential and protected from disclosure by Section 546.702.2 and 3 RSMo. (Cum.Supp.2011), the federal common law privilege of the state secret doctrine invoked by Director Lombardi, and the Lombardi decision issued by the United States Court of Appeals for the Eighth Circuit.

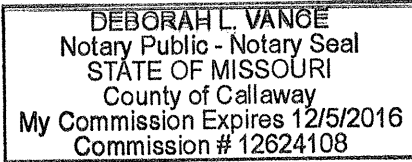
- c. I object to this interrogatory because it seeks information regarding the identity of the compounding pharmacy. This information is confidential and protected from disclosure by Section 546.702.2 and 3 RSMo. (Cum.Supp.2011), the federal common law privilege of the state secret doctrine invoked by Director Lombardi, and the Lombardi decision issued by the United States Court of Appeals for the Eighth Circuit.
- d. Sometime after the morning of 1/6/14
- e. 2/13/14
- f. Thirty days from compounding
- g. Room temperature
- h. 5 grams was used during the execution of Herbert Smulls on January 26, 2014. 5 remaining grams of pentobarbital has been reserved at the request of Plaintiffs' attorneys.

I swear or affirm that the foregoing answers are true and correct.

A handwritten signature in black ink, appearing to read "David Dormire", written over a horizontal line.

David Dormire

Subscribed and sworn to before me this 18 day of February,
2014.



Deborah L. Vance

Notary Public

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that a true and correct copy of the foregoing was electronically filed by using the CM/ECF system on February 19, 2014. This Court's electronic filing system should serve counsel for the plaintiffs listed below, as all are electronic filers.

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EXHIBIT C

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DAVID ZINK, et al.,)
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)
Plaintiffs,)
) No. 2:12-CV-4209-BP
vs.)
)
GEORGE A. LOMBARDI, et al.,)
)
)
Defendants.)

DEPOSITION OF DAVE DORMIRE
Taken on behalf of the Plaintiffs
January 15, 2014
Julie K. Kearns, CCR 993

1 Q. Do you contend that the manufacturer of the raw
2 materials from which the compounded Pentobarbital is made
3 is a member of the execution team?

4 A. The manufacturer?

5 Q. Uh-huh.

6 A. No.

7 Q. Let me draw your attention to, let's see here,
8 page 1310 and 1312 and ask if you know what those
9 documents are?

10 A. 1310 is labels for Pentobarbital and 1312 is
11 also a label.

12 Q. And are they -- is 1312 one of the same labels
13 in 1310 or can we tell?

14 A. They are similar, yes.

15 Q. Okay. So what information is redacted? I mean,
16 again, I'm not asking you to tell me what it says, but
17 what category of information has been redacted there?

18 A. Name of the pharmacy, and its address, I assume,
19 phone numbers, probably. I don't know --

20 Q. Okay.

21 A. -- what all was redacted there.

22 Q. Okay. Do those labels bear a date?

23 A. Yes. November 13, 2013.

24 Q. And when was Joseph Franklin executed?

25 A. I want to say the 20th, but I don't know that

EXHIBIT D

The New York Times<http://nyti.ms/1fnB61R>

ASIA PACIFIC

Medicines Made in India Set Off Safety Worries

By GARDINER HARRIS FEB. 14, 2014

NEW DELHI — India, the second-largest exporter of over-the-counter and prescription drugs to the United States, is coming under increased scrutiny by American regulators for safety lapses, falsified drug test results and selling fake medicines.

Dr. Margaret A. Hamburg, the commissioner of the United States Food and Drug Administration, arrived in India this week to express her growing unease with the safety of Indian medicines because of “recent lapses in quality at a handful of pharmaceutical firms.”

India’s pharmaceutical industry supplies 40 percent of over-the-counter and generic prescription drugs consumed in the United States, so the increased scrutiny could have profound implications for American consumers.

F.D.A. investigators are blitzing Indian drug plants, financing the inspections with some of the roughly \$300 million in annual fees from generic drug makers collected as part of a 2012 law requiring increased scrutiny of overseas plants. The agency inspected 160 Indian drug plants last year, three times as many as in 2009. The increased scrutiny has led to a flood of new penalties, including half of the warning letters the agency issued last year to drug makers.

Dr. Hamburg was met by Indian officials and executives who, shocked by recent F.D.A. export bans of generic versions of popular medicines — like the acne drug Accutane, the pain drug Neurontin and the

antibiotic Cipro — that the F.D.A. determined were adulterated, suspect that she is just protecting a domestic industry from cheaper imports.

“There are some people who take a very sinister view of the F.D.A. inspections,” Keshav Desiraju, India’s health secretary until this week, said in a recent interview.

The F.D.A.’s increased enforcement has already cost Indian companies dearly — Ranbaxy, one of India’s biggest drug manufacturers, pleaded guilty to felony charges and paid a \$500 million fine last year, the largest ever levied against a generic company. And many worry that worse is in store.

“If I have to follow U.S. standards in inspecting facilities supplying to the Indian market,” G. N. Singh, India’s top drug regulator, said in a recent interview with an Indian newspaper, “we will have to shut almost all of those.”

The unease culminated Tuesday when a top executive at Ranbaxy — which has repeatedly been caught lying to the F.D.A. and found to have conditions such as flies “too numerous to count” in critical plant areas — pleaded with Dr. Hamburg at a private meeting with other drug executives to allow his products into the United States so that the company could more easily pay for fixes. She politely declined.

India’s drug industry is one of the country’s most important economic engines, exporting \$15 billion in products annually, and some of its factories are world-class, virtually undistinguishable from their counterparts in the West. But others suffer from serious quality control problems. The World Health Organization estimated that one in five drugs made in India are fakes. A 2010 survey of New Delhi pharmacies found that 12 percent of sampled drugs were spurious.

In one recent example, counterfeit medicines at a pediatric hospital in Kashmir are now suspected of playing a role in hundreds of infant deaths there in recent years.

One widely used antibiotic was found to contain no active ingredient after being randomly tested in a government lab. The test was kept secret

for nearly a year while 100,000 useless pills continued to be dispensed.

More tests of hospital medicines found dozens more that were substandard, including a crucial intravenous antibiotic used in sick infants.

“Some of the fake tablets were used by pregnant women in the post-surgical prevention of infections,” said Dr. M. Ishaq Geer, senior assistant professor of pharmacology at the University of Kashmir. “That’s very serious.”

Investigations of the deaths are continuing, but convictions of drug counterfeiters in India are extremely rare.

Satish Reddy, president of the Indian Pharmaceutical Alliance, said Indian drug manufacturers were better than the F.D.A. now contends. “More rigorous enforcement is needed, for sure, but this impression that India is overrun with counterfeits is unjustified,” Mr. Reddy said.

But Heather Bresch, chief executive of Mylan, which has plants in the United States and India, said regulatory scrutiny outside the United States was long overdue. “If there were no cops around, would everyone drive the speed limit?” Ms. Bresch asked. “You get careless, start taking risks. Our government has enabled this.”

For Dr. Hamburg, the trip is part of a long-running effort to create a global network of drug and food regulators to help scrutinize the growing flood of products coming into the United States, including 80 percent of the seafood consumed in the United States, 50 percent of the fresh fruit, 20 percent of the vegetables and the vast majority of drugs.

She has gone to conclaves of regulators from Europe and elsewhere to coordinate policing, but Indian officials have so far not attended such meetings.

Many of India’s drug manufacturing facilities are of top quality. Cipla, one of the industry’s giants, has 40 plants across the country that together can produce more than 21 billion tablets and capsules annually, and one of its plants in Goa appeared just as sterile, automated and high tech on a recent tour as those in the United States.

Cipla follows F.D.A. guidelines at every plant and on every manufacturing line, and the company exports more than 55 percent of its production, said Yusuf Hamied, the company chairman.

But Benjamin Mwesige, a pharmacist at the Uganda Cancer Institute in Kampala, said in an interview in July that the institute had stopped buying cancer drugs from India in 2011 because it had received shipments of drugs that turned out to be counterfeit and inactive, with Cipla labels that Mr. Mwesige believed were forged.

He became suspicious when doctors began seeing chemotherapy patients whose cancer showed none of the expected responses to the drugs — and who also had none of the usual side effects. The drugs that had been prescribed were among the mainstays of cancer treatment — methotrexate, docetaxel and vincristine. Laboratory tests confirmed that the drugs were bogus, and Mr. Mwesige estimated that in 2011 20 percent of the drugs that the institute bought were counterfeit.

Enforcement of regulations over all is very weak, analysts say, and India's government does a poor job policing many of its industries. Last month, the United States Federal Aviation Administration downgraded India's aviation safety ranking because the country's air safety regulator was understaffed, and a global safety group found that many of India's best-selling small cars were unsafe.

India's Central Drugs Standard Control Organization, the country's drug regulator, has a staff of 323, about 2 percent the size of the F.D.A.'s, and its authority is limited to new drugs. The making of medicines that have been on the market at least four years is overseen by state health departments, many of which are corrupt or lack the expertise to oversee a sophisticated industry. Despite the flood of counterfeit drugs, Mr. Singh, India's top drug regulator, warned in meetings with the F.D.A. of the risk of overregulation.

This absence of oversight, however, is a central reason India's pharmaceutical industry has been so profitable. Drug manufacturers estimate that routine F.D.A. inspections add 25 percent to overall costs. In

the wake of the 2012 law that requires the F.D.A. for the first time to equalize oversight of domestic and foreign plants, India's cost advantage could shrink significantly.

Some top manufacturers are already warning that they may leave, tough medicine for an already slowing economy.

"I'm a great nationalist, an Indian first and last," Dr. Hamied said. "But companies like Cipla are looking to expand their businesses abroad and not in India."

American businesses and F.D.A. officials are just as concerned about the quality of drugs coming out of China, but the F.D.A.'s efforts to increase inspections there have so far been frustrated by the Chinese government.

"China is the source of some of the largest counterfeit manufacturing operations that we find globally," said John P. Clark, Pfizer's chief security officer, who added that Chinese authorities were cooperative.

Using its new revenues, the F.D.A. tried to bolster its staff in China in February 2012. But the Chinese government has so far failed to provide the necessary visas despite an announced agreement in December 2013 during a visit by Vice President Joseph R. Biden Jr., said Erica Jefferson, an F.D.A. spokeswoman.

The United States has become so dependent on Chinese imports, however, that the F.D.A. may not be able to do much about the Chinese refusal. The crucial ingredients for nearly all antibiotics, steroids and many other lifesaving drugs are now made exclusively in China.

Denise Grady contributed reporting from Kampala, Uganda, and Hari Kumar from Srinagar, Kashmir.

A version of this article appears in print on February 15, 2014, on page A1 of the New York edition with the headline: Medicines Made in India Set Off Safety Worries.

CERTIFICATE OF SERVICE

I hereby certify that on February 20, 2014, I electronically filed the foregoing with the Clerk of the Court using the CM/ECF system, which sent notification of such filing to counsel for defendants, who are registered CM/ECF users here.

s/ Matthew B. Larsen
MATTHEW B. LARSEN